DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: September 6, 2002

From: Director, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, HFS-820

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

New Dietary Ingredient:	Nutrichol
Firm:	Tech for Life, Inc.
Date Received by FDA:	January 16, 2002
90-Day Date:	April 16, 2002

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned new dietary ingredient should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Felicia B. Satchell

Felicia B. Satchell

Attachments

95S-0316

RPT 113

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD

MAR 2 9 2002

Jorge Cardenas, MD
Tech for Life
Post Office Box 424
Gilbertsville, Kentucky 42044

Dear Dr. Cardenas:

This is to inform you that the notification, dated October 18, 2001, you submitted pursuant to 21 U.S.C. 350b(a)(2) was received and filed by the Food and Drug Administration (FDA) on January 16, 2002. Your notification concerns the dried powder or extract of the pulverized seeds of the *Persea americana,* or avocado fruit, called "Nutrichol," that you assert is a new dietary ingredient. You propose to market Nutrichol in capsules containing 500 mg of the dried powder or extract of *Persea americana* seed as a dietary supplement with recommendations to take 1000 mg to 2000 mg per day. However, for reasons discussed below, we believe that Nutrichol, as represented in your submission, is a drug under 21 U.S.C. 321(g)(1)(B) (section 201(g)(1)(B) of the Act) because it is intended to reduce blood cholesterol.

Under 21 U.S.C. 321(g)(1)(B), a drug is defined as an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. You indicate in your submission that Nutrichol is a "new dietary herbal supplement to be used in the reduction of blood cholesterol." As a result, your product is intended as treatment for hypercholesterolemia and thus is a drug under 21 U.S.C. 321(g)(1)(B). Accordingly, your product would be subject to regulation under the drug provisions of the Act. If you wish Nutrichol to be evaluated for its use in the treatment of hypercholesterolemia, you should contact FDA's Center for Drug Evaluation and Research, Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

21 U.S.C. 350b(a)(2) requires that a manufacturer or distributor submit certain information to FDA at least 75 days before a new dietary ingredient or a dietary supplement containing a new dietary ingredient is introduced or delivered for introduction into interstate commerce. This information must include the basis on which the manufacturer or distributor has concluded that the new dietary ingredient or a dietary supplement containing it will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C 350b(a)(2), there must be a history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the product's labeling, will reasonably be expected to be safe. If this requirement is not met, the new dietary ingredient or dietary

supplement containing it is deemed to be adulterated under 21 U.S.C. 342(f)(1)(B), because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

As we have stated above, we conclude based on representations in your submission that Nutrichol is a drug. Nonetheless, we have carefully considered the information in your submission concerning whether a dietary supplement containing Nutrichol, if it were allowed to be marketed as a dietary supplement, will reasonably be expected to be safe. We have significant concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing Nutrichol will reasonably be expected to be safe. We explain our concerns below.

Your submission consists of a 2 page cover letter and an attached 12 page "Provisional Patent Application," which you wish to be kept confidential. In the cover letter, your submission states that "*Persea Americana* fruit has been consumed for centuries with a high nutritional value to human health." FDA does not take issue with that statement. However, no information is provided in your submission to provide evidence of, nor an estimate of, normal dietary exposure to dried, pulverized *Persea americana* seeds or extracts of *Persea americana* seeds. The only information in your submission that refers to evidence of human exposure to Nutrichol is a statement that "the pulverized seed product intended to be introduced as a dietary supplement product has been used by many people for an extended period of time with no observed negative effects of any type." The submission then refers to the Provisional Patent Application for details regarding this statement. "Exhibits 1 and 2", cited in the patent application but not included in your submission, are two reports of human studies that purport to demonstrate that dried, pulverized preparations or extracts of *Persea americana* seeds reduce blood pressure and blood cholesterol in individuals having severe and mild hypercholesterolemia. Claims that Nutrichol can significantly reduce blood pressure raise safety concerns if confirmed. However, no information about these studies is provided regarding sample size, study design, analysis, informed consent, or safety to permit an assessment whether your recommended daily consumption of Nutrichol as a dietary supplement product is safe.

In addition, it is not possible to have a reasonable expectation of safety without the knowledge of the nature and identity of the new dietary ingredient. The description of Nutrichol in the Provisional Patent Application includes several formulations and methods of preparation for the new dietary ingredient that include: a dried and pulverized powder of the *Persea americana* seed administered as a tablet, gelcap or component of a meal replacement drink; an aqueous extract prepared by various methods from fresh seed; and an extract of the seed using "suitable organic solvents." Your submission further states that "specific doses and forms of the composition of this invention may be adjusted in accordance with the severity of the hypercholesterolemia to be corrected." This statement infers that the pharmacological properties, and therefore possibly the safety profile, of the final product may vary according to the method by which it is prepared and the formulation chosen. The description of your new dietary ingredient does not address the specific qualitative and quantitative characteristics

of the dietary ingredient that would enable a determination to be made that there is a reasonable expectation of safety. Such information is a necessary prerequisite to meeting the requirements set forth in 21 U.S.C. 350b(a)(2).

Because the information in your submission indicates that your product is a drug and not a dietary supplement, not only would your product be subject to regulation as a drug if marketed, but even insofar as it might be argued that your product is a dietary supplement, the information in your submission does not provide an adequate basis to conclude that Nutrichol, when used under the recommended or suggested conditions of use in the labeling of your product, will reasonably expected to be safe. Therefore, it could be deemed to be adulterated under 21 U.S.C. 342(f)(1)(B) (section 402(f)(1)(B) of the act).

Your submission will be kept confidential for 90 days from the date of receipt, and after April 16, 2002, your submission will be placed on public display at Dockets Management Branch (Docket No. 95S-0316). Commercial and confidential information in the notification and in this communication will not be made available to the public. Prior to April 16, 2002, you may wish to identify in writing specifically what information you believe is proprietary in your current notification for FDA's consideration. Nevertheless, our Center's Freedom of Information Officer has the authority to make the final decision about what information in the notification should be redacted before it is posted at Dockets.

Please contact us at (301) 436-2371, if you have any questions concerning this matter.

Sincerely yours,

Felicia B. Satchell

Felicia B. Satchell
Director
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements

October 18, 2001

Division of Standards and Labeling Regulations
Office of Nutritional Products,
Labeling, and Dietary Supplements (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Dear Sirs:

This is a notification for a new dietary herbal supplement to be used in the reduction of blood cholesterol. This dietary supplement consists of dried and pulverized seeds of the Persea Americana fruit in a capsule form.

The product label for this dietary supplement will contain a disclaimer statement as indicated by FDA regulations: "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease".

Name and complete address.
Jorge Cardenas, MD
Jose V. Bonilla, Ph.D
Tech for life
P.O. Box 424
Gilbertsville, KY 42044

Name of the new dietary ingredient:
The product will be marketed with the name Nutrichol. The dietary supplement is a dried powder or extract of the seed of the Persea Americana fruit for reducing the levels of blood cholesterol.

Description of the dietary supplement:
The dried powder will be offered as a supplement in the form of a capsule.

Conditions of use of the product stated in the labeling:
The dietary supplement is available in a dried powder form and can be taken in amounts ranging from 1000 mg to about 2000 mg per day, or an equivalent (dry weight) amount of seed extract. The product is available in 500-mg capsules. The product label for this dietary supplement will contained a disclaimer: "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease".

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History of use or other evidence of safety:
In terms of documentation which indicates that pulverized seeds of the Persea Americana fruit are acceptable for human consumption and is neither toxic nor hazardous to human health the following information is provided:

1. The Persea Americana fruit has been consumed for centuries with a high nutritional value to human health.

2. The pulverized seed product intended to be introduced as a dietary supplement product has been used by many people for an extended period of time with no observed negative effects of any type.

3. Detailed information on this regard is provided in the attached copy of a provisional patent for this product. ***It is requested that this information be kept confidential until the patent becomes final.***

Should you need any additional information, please contact Tech for Life by phone, e-mail or regular mail at the address below.

Thanks in advance for your help and assistance.

Sincerely,

Jorge Cardenas, M.D.

Jose V. Bonilla, Ph.D.

Tech for life
P.O. Box 424
Gilbertsville, KY 42044
e-mail: bonilla@apex.net
phone: 270-360-7017

PATENT PENDING APPLICATION/SUBMISSION
REDACTED IN ITS ENTIRETY
CONTAINS CONFIDENTIAL COMMERICAL INFORMATION